

## REMARKS

Claims 14, 32, 33 and 34 are currently amended. Claim 31 is canceled. Claims 35 and 36 are new. No new matter is added. It is respectfully submitted that the arguments herein place this case in condition for allowance. Reconsideration of the application is urged.

### I. The Rejections of Claims under 35 U.S.C. 102(b)

Claims 14, 15, 17, 18, 20 and 34 were rejected as anticipated by Tothill *et al.* (Enzyme and Microbial Technology, 1997, p.590-596) (hereinafter referred to as "Tothill"). Claims 14, 17, 18, 19, 20 and 34 were rejected as anticipated by U.S. 5,260,202 (hereinafter referred to simply as "Clark"). Claims 14, 17, 18 and 34 were rejected as anticipated by DD 0153495.

Independent claims 14 and 34 are currently amended. Reconsideration is urged.

### II. The Rejection of Claims 14-33 under 35 U.S.C. 103

Claims 14-33 are rejected under 35 U.S.C. 103(a) as being obvious in light of Kaasgaard *et al.*, U.S. patent publication no. 2004/0175812 (hereinafter simply referred to as "Kaasgaard"). Applicants respectfully traverse this rejection.

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 298, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). The Supreme Court stated that "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. The Court also noted that "[t]o facilitate review, this analysis should be made explicit." *Id.* at 418. (Citing *In re Kahn*, 441 F.3d 977, 988 (Fed Cir. 2006) ("[R]ejections on

obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). However, "the analysis need not seek out precise teachings directed to a specific subject matter of the challenged claim, for a court can take into account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* Further, general statements of obviousness lack the specificity required to support a legal conclusion of obviousness and are insufficient to establish *prima facie* obviousness. See *KSR* (holding that a "patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art . . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does."

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. See *Oetiker*, 977 F.2d at 1445; see also *Piasecki*, 745 F.2d at 1472. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *Id.*

The Examiner has failed to make a *prima facie* case of obviousness, and the rejection is in error.

Without any scientific rationale, the Examiner erroneously equates prior to a recovery step with during fermentation. In other words, the Examiner is maintaining the position that "prior to the recovery step" necessarily means "during fermentation".

Kaasgaard does not make obvious the present disclosure. As previously explained the present invention, among other things, includes adding one or more listed compounds to the culture medium before and/or during fermentation. Applicants have discovered that the specified compounds are suitable for use during fermentation-- thus can be added before and/or during fermentation. Conversely, Kaasgaard is deficient in that it limits disclosure of adding a polyol, and/or a carbohydrate, and/or a derivative thereof, to the culture solution during recovery processing. See, e.g., paragraph 9 of Kassgaard, which describes added certain compounds to the culture solution prior to, or immediately after, said recovery step. Further, paragraph 12 describes, *inter alia*, avoiding formation of protein crystals/precipitates during recovery processing.

Moreover, nowhere does Kaasgaard, including paragraphs 0007-0009, 0051-0057, 0080-0096 describe anything other than adding the compounds prior to a specified recovery step (during recovery processing). The recovery steps of Kaasgaard are specific, and set forth for example in paragraphs [0045], [0046], [0047], [0048], [0049] and [0050]. Nowhere does Kaasgaard describe adding one or more of the compounds to the culture medium before and/or during fermentation, as required by the instant claims. Consequently, Kaasgaard teaches away from the present disclosure.

Inventor Kaasgaard previously explained that one would not infer from the Kaasgaard reference that adding the polyols and/or carbohydrates disclosed in Kaasgaard prior to a recovery step would mean adding the compounds during fermentation. Rather Kaasgaard is limited to adding the polyols and/or carbohydrates prior to the specified recovery steps. See for paragraph 5 of the previously submitted Kaasgaard declaration. In other words, each of the specified recovery steps occurs after fermentation. Applicants believe that if one were to review the reference as a whole, there is no indication that any of polyols and/or carbohydrates of Kaasgaard should be added before and/or during fermentation. Accordingly, Kaasgaard does not anticipate the claimed invention and reconsideration is urged.

To the extent that the Examiner maintains that the addition of polyols before the recovery step can **only** be occurring during fermentation, Applicants respectfully disagree. In paragraphs 45-50, Kaasgaard discloses various recovery steps in the recovering processing. In accordance with Kaasgaard, ingredients may be added, *e.g.*, before concentration (recovery processing step 4), or filtration (recovery processing step 5). Accordingly, the Examiner has erred by maintaining that the addition of polyols before the recovery step can only be occurring during fermentation.

Applicants note that Kaasgaard is devoid of any suggestion to add anything to the fermentation as advanced by the Examiner, except from using Applicants' disclosure as a template through hindsight reconstruction of Applicants claim. Thus, the Examiner has erroneously retraced the path of the inventor with hindsight --discounting the number of complexities of the alternatives in order to conclude that the specifically claimed methodology was obvious. This reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a).

Applying a non-rigid TSM analysis, one of ordinary skill in the art would not be motivated by the Kaasgaard reference to modify the methodology of Kaasgaard to somehow arrive at the Applicants claimed invention including adding one or more listed compounds to the culture medium before and/or during fermentation. There is certainly no suggestion to do so in the reference.

Applicants further request reconsideration of the Declaration of inventor Kaasgaard.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. § 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

**III. The Rejection of Claims 14, 17, 19, 20, 21, 32, 33 and 34 under 35 U.S.C. 103(a).**

Claims 14, 17, 19, 20, 21, 32, 33 and 34 are rejected under 35 U.S.C. 103(a) as being obvious in light of CH 667673. Independent claims 14, 32, 33 and 34 are currently amended. Reconsideration is urged.

**IV. The Rejection of Claims 14, 15, 17, 18, 20 and 34 under 35 U.S.C. 103(a).**

Claims 14, 15, 17, 18, 20 and 34 are rejected under 35 U.S.C. 103(a) as being obvious in light of Clarke. Independent claims 14, and 34 are currently amended. Reconsideration is urged.

**V. The Rejection of Claims 14-34 under 35 U.S.C. 103(a).**

Claims 14- 34 are rejected under 35 U.S.C. 103(a) as being obvious in light of DD 0153495 in view of Schreiber (U.S. 4,016,039), Brothers *et al.* (U.S. 4,673,647), GB 1001173 and Boyer *et al.* (5,385,837).. Independent claims 14, 32, 33 and 34 are currently amended. Reconsideration is urged.

**VI: New claims**

New claims 35 and 36 are added. The USPTO is authorized to charge the deposit account of Novozymes North America, Inc, 50-1701 should any additional fees be due.

## VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: January 28, 2010

/Michael W. Krenicky Reg # 45411/  
Michael W. Krenicky Reg. # 45,411  
Novozymes North America, Inc.  
500 Fifth Avenue, Suite 1600  
New York, NY 10110  
(212)840-0097